

OPEXA THERAPEUTICS, INC.

FORM 8-K/A (Amended Current report filing)

Filed 11/09/07 for the Period Ending 08/14/07

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K/A

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 14, 2007



OPEXA THERAPEUTICS

Opexa Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Texas
(State or Other Jurisdiction of Incorporation)

001-33004
(Commission File Number)

76-0333165
(I.R.S. Employer Identification No.)

2635 N. Crescent Ridge Drive
The Woodlands, Texas
(Address of Principal Executive Office)

77381
(ZipCode)

Registrant's telephone number, including area code: **(281) 272-9331**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2 below):

- ☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communication pursuant to Rule 144d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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EXPLANATORY NOTE:

Opexa Therapeutics, Inc.'s ("Opexa") Current Report on Form 8-K filed on October 3, 2007 is hereby being amended to correct the Item under which the disclosure was made. The original Form 8-K inadvertently listed the disclosure under Item 2.02. The information disclosed in the 8-K was information previously publicly disclosed and did not qualify for disclosure under Section 2.02, thus Opexa is filing this amendment properly filing the information under Section 8.01.

Item 8.01. Other Events.

On August 14, 2007 Registrant filed its Quarterly Report on Form 10-QSB for the quarter ended June 30, 2007. On August 14, 2007, Registrant announced its results of operations in a press release. A copy of the press release is attached as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(c) Exhibit 99.1

The following exhibit is to be filed as part of this 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued August 14, 2007

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ David B. McWilliams
David B. McWilliams
President and Chief Executive Officer

DATE: November 9, 2007

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued August 14, 2007



OPEXA THERAPEUTICS

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Opexa Reports Second Quarter 2007 Financial Results

THE WOODLANDS, Texas (Aug. 14, 2007) – Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company involved in the development and commercialization of cell therapies, today reported financial results for the quarter ended June 30, 2007 and provided an update on its progress.

Highlights of the second quarter of 2007 and recent weeks include:

- Positive top-line data from Phase I/II extension trial with Tovaxin® for multiple sclerosis
- Completion of patient enrollment in Phase IIb trial with Tovaxin for multiple sclerosis
- Opexa delivers two scientific presentations on progress of development of monocyte-derived pancreatic islet cells for diabetes
- Appoints clinical advisory board to support diabetes program

David McWilliams, chief executive officer of Opexa, commented, “We reached several important milestones during the quarter as we continued to advance the development of our technologies. In the case of Tovaxin, our lead program for the treatment of multiple sclerosis, we completed patient enrollment in a 150-patient Phase IIb safety and efficacy study. The trial design is a U.S. multicenter, randomized, double-blind, placebo-controlled study of subcutaneous Tovaxin in subjects with Clinically Isolated Syndrome (CIS) or Relapsing/Remitting Multiple Sclerosis (RRMS). We expect top-line data from this trial to be available in the second half 2008. We also announced positive top-line data in an open-label Phase I/II extension clinical trial of Tovaxin. In this one-year, eight-subject extension clinical trial of relapsing remitting (RRMS) and secondary progressive (SPMS) subjects, Tovaxin therapy was shown to be safe and effective, experiencing a greater than 90% reduction in annualized relapse rate.

“We have also made excellent progress with our stem cell program, particularly in the area of diabetes,” Mr. McWilliams continued. In June, we made two very important presentations to two separate stem cell conferences, which covered our recent research derived from our innovative adult stem cell program regarding the development of adult monocyte-derived islets, as beta-cell replacement therapy for diabetes mellitus. We are very encouraged by the preclinical data we are assembling and during the quarter appointed a clinical advisory board specifically to help us advance our diabetes program.”

Second Quarter Financial Results

Opexa reported no revenues for the three months ended June 30, 2007 or in the comparable prior-year period. General and administrative expenses were \$865,744 in the second quarter of 2007, compared with \$3,169,832 in the second quarter of 2006. The decline is primarily due to a decrease in stock compensation expense, professional service fees and overhead expenses. The Company expects future general and administrative expenses to be higher as it prepares for commercialization of its products.

Research and development expenses were \$3,712,208 in the 2007 second quarter, compared with \$1,554,912 in the second quarter of 2006. The increase primarily was related to the costs of the Phase IIb clinical trial for Tovaxin, research and development in support of pre-clinical diabetes stem cell therapies and stock compensation expense recorded in 2007.

Opexa reported a net loss for the second quarter of 2007 of \$4,906,076, or \$0.73 per share, compared with a net loss for the second quarter of 2006 of \$8,475,868 or \$1.40 per share. The decrease in net loss primarily was due to a reduction in stock-based compensation expense and loss on derivative instruments, offset in part by the increase in costs of the Phase IIb trial for Tovaxin.

The Company had cash and cash equivalents of \$8,918,101 as of June 30, 2007, compared with \$12,019,914 million as of December 31, 2006.

Year-to-Date Financial Results

Opexa reported no revenues in the six months ended June 30, 2007 or in the comparable prior-year period. General and administrative expenses for the six months ended June 30, 2007 were \$1,715,530, compared to \$4,245,714 for the six months ended June 30, 2006. The decrease in G&A expenses was primarily due to a decrease in stock compensation expense, professional service fees and overhead expenses. The Company anticipates increases in general and administrative expenses as it continues to develop and prepare for commercialization of its technology.

Research and development expenses were \$6,959,674 for the six months ended June 30, 2007, compared to \$2,293,362 for the six months ended June 30, 2006. The increase in R&D expenses was primarily due to the costs of conducting the Phase IIb clinical trial for Tovaxin, research and development in support of pre-clinical diabetes stem cell therapies and stock compensation expense recorded in 2007.

Opexa reported a net loss for the six months ended June 30, 2007 of \$9,288,064 or (\$1.39) per share, compared with a net loss for the six months ended June 30, 2006 of \$10,446,178, or (\$2.57) per share. The decrease in net loss was primarily due to a reduction in stock-based compensation expense and loss on derivative instruments, offset in part by the increase in costs of the Phase IIb trial for Tovaxin.

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as MS, rheumatoid arthritis, and diabetes. The Company is focused on autologous cellular therapy applications of its proprietary T-cell and stem cell therapies. The Company's lead product, Tovaxin, a T-cell therapy for multiple sclerosis is in Phase IIb trials. The Company holds the exclusive worldwide license for adult multipotent stem cells derived from mononuclear cells of peripheral blood. The technology allows large quantities of monocyte derived stem cells to be produced efficiently for use in autologous therapy, thus circumventing the threat of rejection. The Company is in preclinical development for diabetes mellitus.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements about Opexa Therapeutics' growth and future operating results, discovery and development of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. These forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including those relating to Opexa Therapeutics' ability to obtain additional funding, develop its stem cell technologies, achieve its operational objectives, and obtain patent protection for its discoveries, that may cause Opexa Therapeutics' actual results to be materially different from any future results expressed or implied by such forward-looking statements. Opexa Therapeutics undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

(Tables to Follow)

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF EXPENSES
Three and Six Months ended June 30, 2007 and 2006 and the
Period from January 22, 2003 (Inception) to June 30, 2007
(unaudited)

	Three Months Ended June 30, 2007	Three Months Ended June 30, 2006	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006	Inception through June 30, 2007
Research and development	\$ 3,712,208	\$ 1,554,912	\$ 6,959,674	\$ 2,293,362	\$ 19,388,583
General and administrative	865,744	3,169,832	1,715,530	4,245,714	15,921,999
Depreciation and amortization	462,370	460,442	923,476	892,775	4,742,299
Loss on disposal of assets	<u>4,034</u>	<u>-</u>	<u>4,034</u>	<u>362</u>	<u>486,343</u>
Operating loss	(5,044,356)	(5,185,186)	(9,602,714)	(7,432,213)	(40,539,224)
Interest income	141,971	198,785	320,794	218,406	1,097,015
Other income	-	43,065	-	46,450	77,003
Loss on derivative liability	-	(3,532,348)	-	(3,278,208)	-
Interest expense	(3,691)	(184)	(6,144)	(613)	(8,245,107)
Net loss	<u>\$ (4,906,076)</u>	<u>\$ (8,475,868)</u>	<u>\$ (9,288,064)</u>	<u>\$ (10,446,178)</u>	<u>\$ (47,610,313)</u>
Basic and diluted loss per share	\$ (0.73)	\$ (1.40)	\$ (1.39)	\$ (2.57)	N/A
Weighted average shares outstanding	6,696,784	6,039,561	6,696,784	4,063,473	N/A

OPEXA THERAPEUTICS, INC.
(a development stage company)
BALANCE SHEETS
(unaudited)

	<u>June 30,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,918,101	\$ 12,019,914
Investment in marketable securities	-	2,952,096
Other current assets	<u>718,876</u>	<u>472,881</u>
Total current assets	9,636,977	15,444,891
Intangible assets, net accumulated amortization of \$4,358,119 and \$3,533,568, respectively	23,898,652	24,723,203
Property & equipment, net accumulated depreciation of \$483,275 and \$395,284, respectively	<u>1,371,007</u>	<u>1,361,377</u>
Total assets	<u><u>\$ 34,906,636</u></u>	<u><u>\$ 41,529,471</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,273,766	\$ 868,862
Stock payable	112,440	112,440
Accrued expenses	842,995	135,069
Note payable	1,500,000	1,500,000
Current maturity of loan payable	55,928	14,080
Derivative liability	<u>-</u>	<u>6,656,677</u>
Total current liabilities	3,785,129	9,287,128
Long term liabilities:		
Loan payable	<u>191,680</u>	<u>96,242</u>
Total liabilities	<u><u>3,976,809</u></u>	<u><u>9,383,370</u></u>
Commitments and contingencies	-	-
Stockholders' equity:		
Convertible preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.50 par value, 100,000,000 shares authorized, 6,696,784 shares issued and outstanding	3,348,351	3,348,351
Additional paid in capital	75,191,789	63,118,180
Deficit accumulated during the development stage	<u>(47,610,313)</u>	<u>(34,320,430)</u>
Total stockholders' equity	<u>30,929,827</u>	<u>32,146,101</u>
Total liabilities and stockholders' equity	<u><u>\$ 34,906,636</u></u>	<u><u>\$ 41,529,471</u></u>

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